

UPAP0003-100  
Application No.: 10/076,900

PATENT  
Filed: February 14, 2002

### AMENDMENTS TO THE CLAIMS

Please amend claims 15, 16, 106 and 114, cancel claims 44, 50, 54, 82, 84, 86, 88, 94, 98, 100, 104 and 105 without prejudice, and add new claims 115-121 as follows.

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

1-14. (Canceled)

15. (Currently Amended) A method of inducing in an individual an immune response against an antigen

wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytotoxic T lymphocytes;

the method comprising the step of administering by topical or lavage administration to mucosal tissue of said individual, said mucosal tissue selected from the group consisting of rectal, vaginal, urethral, sublingual and buccal, a nucleic acid molecule that is free of an infectious-agent and comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce an immune response against said antigen wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response;

wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.

16. (Currently Amended) A The method of claim 15 inducing in an individual an immune response against an antigen

wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytotoxic T lymphocytes;

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the method comprising the step of administering by topical or lavage administration to mucosal tissue of said individual, said mucosal tissue selected from the group consisting of rectal, vaginal, urethral, sublingual and buccal, a nucleic acid molecule that is free of an infectious-agent and comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce an immune response against said antigen wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response;

wherein the antigen is a pathogen antigen and said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.

17-38. (Canceled)

39. (Previously Presented) The method of claim 15 wherein the immune response is a therapeutically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a therapeutically effective immune response against said antigen.

40. (Previously Presented) The method of claim 39 wherein the antigen is a pathogen antigen.

41. (Previously Presented) The method of claim 40 wherein the pathogen antigen is a viral antigen.

42. (Previously Presented) The method of claim 41 wherein the viral antigen is an antigen from human immunodeficiency virus.

43. (Previously Presented) The method of claim 42 wherein antigen from human immunodeficiency virus comprises an epitope of human immunodeficiency virus protein gp160.

44. (Canceled)

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45. (Previously Presented) The method of claim 15 wherein the immune response is a prophylactically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a prophylactically effective immune response against said antigen.

46. (Previously Presented) The method of claim 45 wherein the antigen is a pathogen antigen.

47. (Previously Presented) The method of claim 46 wherein the pathogen antigen is a viral antigen.

48. (Previously Presented) The method of claim 47 wherein the viral antigen is an antigen from human immunodeficiency virus.

49. (Previously Presented) The method of claim 48 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

50. (Canceled)

51. (Previously Presented) The method of claim 16 wherein the pathogen antigen is a viral antigen.

52. (Previously Presented) The method of claim 51 wherein the viral antigen is an antigen from human immunodeficiency virus.

53. (Previously Presented) The method of claim 52 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

54-80. (Canceled)

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81. (Previously Presented) The method of claim 15 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.

82. (Canceled)

83. (Previously Presented) The method of claim 81 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected from the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.

84. (Canceled)

85. (Previously Presented) The method of claim 83 wherein said protein is IL-12.

86. (Canceled)

87. (Previously Presented) The method of claim 16 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.

88. (Canceled)

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89. (Previously Presented) The method of claim 87 wherein the pathogen antigen is a viral antigen.

90. (Previously Presented) The method of claim 89 wherein the viral antigen is an antigen from human immunodeficiency virus.

91. (Previously Presented) The method of claim 90 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

92. (Canceled)

93. (Previously Presented) The method of claim 87 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected from the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.

94. (Canceled)

95. (Previously Presented) The method of claim 93 wherein the pathogen antigen is a viral antigen.

96. (Previously Presented) The method of claim 95 wherein the viral antigen is an antigen from human immunodeficiency virus.

97. (Previously Presented) The method of claim 96 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

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98. (Canceled)

99. (Previously Presented) The method of claim 93 wherein said protein is IL-12.

100. (Canceled)

101. (Previously Presented) The method of claim 99 wherein the pathogen antigen is a viral antigen.

102. (Previously Presented) The method of claim 101 wherein the viral antigen is an antigen from human immunodeficiency virus.

103. (Previously Presented) The method of claim 102 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.

104-105. (Canceled)

106. (Currently Amended) The method of claim ~~16~~ 105 wherein the pathogen antigen is a viral antigen.

107. (Previously Presented) The method of claim 106 wherein the viral antigen is an antigen from human immunodeficiency virus.

108. (Previously Presented) The method of claim 15 wherein said mucosal tissue is selected from the group consisting of rectal, vaginal, urethral and said nucleic acid molecule is administered by suppository.

109. (Previously Presented) The method of claim 108 wherein said mucosal tissue is rectal.

110. (Previously Presented) The method of claim 108 wherein said mucosal tissue is vaginal.

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111. (Previously Presented) The method of claim 108 wherein said mucosal tissue is urethral.
112. (Previously Presented) The method of claim 15 wherein said mucosal tissue is selected from the group consisting of sublingual and buccal.
113. (Previously Presented) The method of claim 112 wherein said mucosal tissue is sublingual.
114. (Currently Amended) The method of claim 112 ~~143~~ wherein said mucosal tissue is buccal.
115. (New) The method of claim 16 wherein said mucosal tissue is selected from the group consisting of rectal, vaginal, urethral and said nucleic acid molecule is administered by suppository.
116. (New) The method of claim 115 wherein said mucosal tissue is rectal.
117. (New) The method of claim 115 wherein said mucosal tissue is vaginal.
118. (New) The method of claim 115 wherein said mucosal tissue is urethral.
119. (New) The method of claim 16 wherein said mucosal tissue is selected from the group consisting of sublingual and buccal.
120. (New) The method of claim 119 wherein said mucosal tissue is sublingual.
121. (New) The method of claim 120 wherein said mucosal tissue is buccal.